In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 22-0389V

SHEILA PORTER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 9, 2024

Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for Petitioner.

Dorian Hurley, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On April 4, 2022, Sheila Porter filed a Petition under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"); *see* Section 11(c)(1)(D)(i). Petitioner alleges that she received an influenza ("flu") vaccine in her right arm on September 9, 2020, which was followed within forty-eight (48) hours by the onset of a right shoulder injury related to vaccine administration ("SIRVA") - a Vaccine Injury Table claim. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

[1] Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Under the Act's more-likely-than-not standard, and for the following reasons, I conclude that the vaccine was administered to Petitioner's right arm (notwithstanding one conflicting, handwritten vaccine administration record), and that her right shoulder pain began within 48 hours thereafter (notwithstanding a treatment delay). Based on the lack of any other objections from Respondent, along with an independent review of the record, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim – making her entitled to compensation.

I. Procedural History

After the case was assigned to the SPU in June 2022, situs and onset were identified as potential obstacles to the Table SIRVA claim. Respondent's ("Resp.") Status Report filed Oct. 7, 2022 (ECF No. 13); *accord* Resp. Rule 4(c) Report filed Aug. 16, 2023 (ECF No. 23) (formally opposing compensation); Show Cause Order issued Nov. 27, 2023 (ECF No. 24). Both parties submitted briefing. Brief filed Jan. 24, 2024 (ECF No. 25); Response filed Feb. 29, 2024 (ECF No. 29); Reply filed Mar. 15, 2024 (ECF No. 31). The matter is ripe for adjudication.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

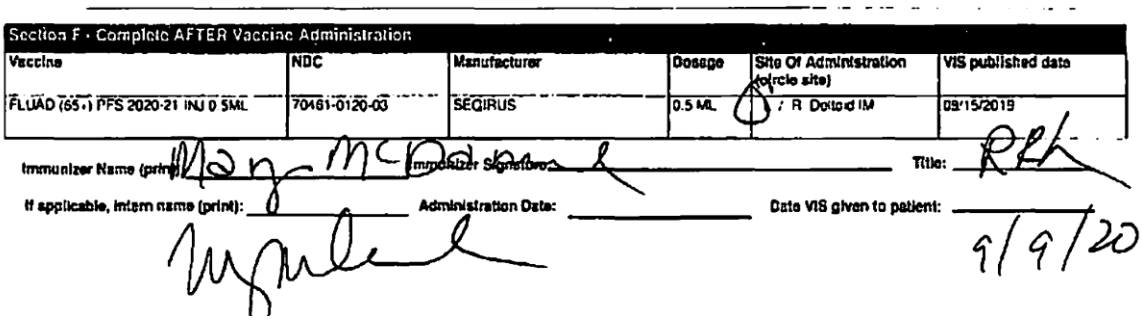
III. Evidence

I have reviewed all of the filings submitted by both parties to date. The below summary focuses on their disputed issues (site and onset).

A. Contemporaneous Medical Records

Petitioner was born in 1948. She is right-handed, and had no history of right shoulder pain or dysfunction. *See generally* Ex. 3. During a January 2020 annual evaluation with her established primary care physician ("PCP"), Petitioner complained of generalized fatigue and depression since her husband's recent death. *Id.* at 38 – 40.

On September 9, 2020, at a Walgreens in her home state of Arizona, Petitioner filled out a consent form to receive a flu vaccine. Ex. 2 at 5. After signing her name, she wrote an incorrect date of "3/9/20." *Id.* On the form's next page, a Walgreens employee handwrote certain information, including a circle roughly around the letter "L" for a left deltoid site of administration:



Id.; *see also* Ex. 11 at 3 (billing records confirming a vaccination date of September 9, 2020). Petitioner did not have any medical encounters for any reason for six months thereafter – except for receiving her first two COVID-19 vaccines (with no administration site specified) at "Embry Health" on February 20 and March 30, 2021. Ex. 15 at 1.

Next, at an in-person annual evaluation on March 31, 2021 (now more than six months post-vaccination), the PCP recorded: "[Petitioner] had a flu shot in September and since then, she has had pain in the rt [right] arm and since then, she has had pain in the rt [right] shoulder going to the neck and back and the arm and she is not able to lift her arm and that has affected her ability to do her daily activities. She is frustrated with that." Ex. 3 at 33. A physical exam confirmed left shoulder pain and reduced range of motion ("ROM"). *Id.* at 35. The primary care physician ("PCP") assessed adhesive capsulitis, and ordered an MRI of the shoulder. *Id.*

The April 6, 2021, MRI report lists a clinical history of "[a]dhesive capsulitis. Intermittent dull achy pain around right shoulder since September 2020 after received flu shot." Ex. 4 at 6. The MRI findings were suggestive of tendinopathy, osteoarthritis, a superior labrum tear, bursitis, and possible adhesive capsulitis. Ex. 4 at 6; *see also* Ex. 3 at 29 – 31 (PCP telehealth follow-up and orthopedics referral). On April 19, 2021, the PCP recorded that Petitioner's right shoulder remained painful and hard to lift, and Petitioner was referred to an orthopedist. Ex. 3 at 29.

At a May 5, 2021, orthopedics initial evaluation, Petitioner reported right shoulder pain since September 2020 after getting a flu shot a little higher than expected. Ex. 5 at 22. She was noted to be right-handed. An exam found reduced ROM on the right compared to the left shoulder. *Id.* at 23 – 24. The orthopedist reviewed the recent MRI, diagnosed adhesive capsulitis, and recommended physical therapy ("PT") within the same facility (OrthoArizona). *Id.*

From May 14 – July 15, 2021, Petitioner attended 13 PT sessions for her right shoulder injury. *See generally* Exs. 5, 6. The records reflect the same history that the injury had been present since her receipt of a flu shot higher than expected, in September 2020. Ex. 5 at 17. The discharge summary reflects that Petitioner had "met all goals with PT" and that she would continue a home exercise program. Ex. 6 at 5 – 6.[4]

B. Later Statements[5]

With regard to situs, Petitioner contends that the written vaccine administration record is incorrect. Ex. 1 at ¶ 7. She recalls that the Walgreens nurse initially prepared to

[4] I have also reviewed the records of medical encounters for unrelated complaints, occurring between mid-2021 – early 2022. *See* Rule 4(c) Report at 4 – 5 (internal citations omitted). These records are not relevant to the disputed situs and onset issues, or otherwise to the Table SIRVA entitlement determination.

[5] Apart from Petitioner's first statement from March 2022 (Ex. 1), the statements were prepared in March 2023 (Exs. 17 – 22). All are sworn under penalty of perjury. *See* 28 U.S.C.A. § 1746 (providing that such a declaration may be afforded like force and effect as a notarized affidavit).

administer the flu vaccine on her *left*, non-dominant side. Ex. 22 at ¶ 4. But the nurse switched sides at the request of Petitioner, who hoped to soon receive COVID vaccines in her left arm - while remaining in her car at a drive-in clinic. *Id.* Petitioner believes that the nurse failed to record this change of plan on the flu vaccine's administration record. *Id.* Petitioner also believes that the nurse administered the vaccine unusually high, in her right shoulder rather than the deltoid muscle. *Id.*

With regard to onset, Petitioner recalls that her right shoulder pain began on the same day as the vaccination. Ex. 1 at ¶ 8. But her PCP's office was not offering in-person evaluations in the fall of 2020 because of the Pandemic, and she did not believe that her shoulder could be properly evaluated virtually. Ex. 22 at ¶ 6. She took Tylenol to help relieve her pain until she could schedule an in-person evaluation with her PCP. *Id.*

Additionally, Petitioner's daughter and four different friends uniformly recall that starting in or around September 2020, Petitioner recounted a vaccine's administration into her right shoulder (higher than expected), which had caused acute and persisting right shoulder pain. *See generally* Ex. 17 – 21. These witnesses describe regular conversations as well as in-person encounters with Petitioner, during which they personally observed her right shoulder injury. *See, e.g.*, Ex. 17 at ¶ 6 (friend's recollection of a walk after receiving their respective flu shots in September 2020); Ex. 18 at ¶ 5 (daughter's description of living about three blocks away from Petitioner); Ex. 19 at ¶ 5, and Ex. 20 at ¶ 5 (friends' descriptions of lunches once or twice a month); Ex. 21 at ¶¶ 4, 9 (friend's description of living 10 miles away, and being driven by Petitioner).[6]

One friend also recalls that in late January 2021, Petitioner asked for help finding somewhere to receive COVID-19 vaccinations in her left arm without getting out of the car. Ex. 19 at ¶ 7. The friend identified a new drive-in clinic operated by Embry Women's Health, and Petitioner got an appointment as soon as it opened. *Id.*

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[6] Respondent identified an internal inconsistency within one friend's statement. *Compare* Ex. 17 at ¶¶ 5 – 6 (recalling that her flu shot occurred first) and *id.* at ¶ 8 (recalling that Petitioner was "very concerned because of her ongoing pain while my pain had gone away, especially since *she had gotten her flu shot before I had gotten mine*") (emphasis added). But this single inconsistency does not render this friend's statement unreliable, as Respondent argues. Response at 10. The friend's recollections are otherwise detailed and logical. She shared that her shoulder had been "a little sore for a couple of days but had cleared up and was back to normal." Ex. 17 at ¶ 7. In comparison, Petitioner's shoulder pain was more severe, still present about a week after vaccination, and she was moreover concerned that the site was unusually high – all helping to explain Petitioner's concern during their walk together. *Id.*

Respondent also suggests that these statements are less reliable, because they were prepared for the purposes of litigation. Rule 4(c) Report at 11 – 12 and Response at 9 – 10 (internal citations omitted). But Petitioner argues that her friends and daughter are disinterested parties. Reply at 7.

There is also corroborating evidence that Petitioner's primary care practice was closed to in-person visits, and only offering telehealth services until about March 2021. Ex. 17 at ¶¶ 10 (daughter's description of using the same practice); Ex. 14 at 1 (PCP's letter).

IV. Analysis

A. Vaccine Administration Site

A petitioner asserting a SIRVA claim bears the burden of establishing the site of vaccine administration. Section 11(c)(1); 42 C.F.R. § 100.3(c)(10)(iii) (referring to "the shoulder *in which the* intramuscular vaccine *was administered*") (emphasis added).

Based on my experience with SIRVA cases (over 2,000 within SPU since my appointment as Chief Special Master, additional cases handled within chambers, and review of opinions issued by other special masters), I deem it not unusual for vaccine administration site information to be inaccurately recorded – especially within electronic records. Handwritten notations of situs, by contrast, are generally deemed to be more reliable[7] - but they too are capable of being rebutted by the weight of other evidence.[8]

Here, the Walgreens vaccine administration record is the most contemporaneous evidence of situs. Respondent argues that this "clearly" identifies the left deltoid. Rule 4(c) Report at 11; Response at 9. And indeed, the situs is indicated by a handwritten circle – the kind of evidence often given weight in these kinds of disputes. But Petitioner counters that the record is actually "ambiguous… hastily completed… sloppily completed," and therefore should not dictate the situs finding. Reply at 1; *see also id* at 4. Indeed, there are other inaccuracies in this record. For example the employee responsible for the record did not correct the incorrect date of Petitioner's consent for vaccination. And the employee's handwritten circle around the "L," and her signature block, are somewhat imprecise. *Accord Toothman*, 2024 WL 2698520, at *4 (assigning less weight to a "handwritten entry on an otherwise haphazardly completed form… containing entries listed diagonally and not in the allotted spaces").

[7] *See, e.g.*, *Schmidt v. Sec'y of Health & Hum. Servs.*, No. 17-1530V, 2021 WL 5226494, at *8 (Fed. Cl. Spec. Mstr. Oct. 7, 2021); *Marion v. Sec'y of Health & Hum. Servs.*, No. 19-0495V, 2020 WL 7054414 at *8 (Fed. Cl. Spec. Mstr. Oct. 27, 2020); *Daugherty v. Sec'y of Health & Hum. Servs.*, No. 15-1919V, 2024 WL 3416068, at *5 – 6 (Fed. Cl. Spec. Mstr. June 5, 2024).

[8] *See, e.g.*, *Rizvi v. Sec'y of Health & Hum. Servs.*, No. 21-0881V, 2022 WL 2284311 at * 3 (Fed. Cl. Spec. Mstr. May 13, 2022); *Toothman v. Sec'y of Health & Hum. Servs.*, No. 22-0207V, 2024 WL 2698520, at *4 (Fed. Cl. Spec. Mstr. Apr. 19, 2024); *Supernaw v. Sec'y of Health & Hum. Servs.*, No. 20-1517V, at *5 – 6, 2024 WL 3739291 (Fed. Cl. Spec. Mstr. July 10, 2024).

The Federal Circuit has counseled that. patient histories "in general, warrant consideration as trustworthy evidence… [as they] contain information supplied to… health professionals to facilitate diagnosis and treatment." *Cucuras*, 993 F.2d at 1528. Thus, I am required to consider Petitioner's later histories of an injurious right-sided vaccination to at least three different medical providers (even though those histories were given over six and one-half months later).

There is also witness statement evidence supporting Petitioner's situs contention. While the five fact witnesses do not claim to have personally witnessed the vaccination, they consistently recall Petitioner voicing concerns that a *right-sided* vaccination had caused her shoulder injury, beginning much earlier than the medical records.

I have questioned Petitioner's explanation that she opted for a right-arm vaccination because she wanted to receive COVID-19 vaccines in her left arm in the near future. Show Cause Order at 2. Petitioner's Brief does not address this issue. *See generally* Brief. Respondent observes that the FDA issued the first emergency use authorization for public distribution of COVID-19 vaccinations in December 2020, and Petitioner did not actually receive her first COVID-19 dose until February 20, 2021. Response at 12 – 13 (internal citations omitted). Thus, there is a slight pretextual quality to Petitioner's allegation that she intended to "preserve" her left arm for a later, drive-through vaccination event, when this did not occur for some time thereafter. However, it is also true that Petitioner's state's health department had already published considerations for curbside or drive-through immunization services. Reply at 6, citing Ex. 26. Overall, however, even if I discount Petitioner's argument on this specific point, there is enough other evidence to preponderate on situs in her favor.

B. Onset

Petitioner must also establish that her right shoulder pain began within forty-eight (48) hours of vaccination. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii). Respondent disputes this requirement in light of the initial 203-day delay in evaluation by Petitioner's PCP (who was offering telehealth appointments) or any other provider. Response at 13 – 14. But Petitioner explains that she was able to manage her pain with Tylenol. She did not believe that a telehealth evaluation would be helpful, and she waited until her PCP was again offering in-person appointments. Ex. 22 at ¶ 6. Her PCP has confirmed that in-person appointments were not available until March 2021. Ex. 14. Petitioner's explanation is logical considering the relatively low level of pain described.

Respondent's characterization of the medical record histories, as insufficiently vague, is unpersuasive. Ms. Porter consistently reported left shoulder pain "after" and "since" the flu shot. *See, e.g.*, Ex. 3 at 33; Ex. 4 at 6; Ex. 5 at 22; Ex. 23 at 17. I have repeatedly held that such evidence supports a likelihood of onset within 48 hours. *See, e.g.*, *Rodriguez v. Sec'y of Health & Hum. Servs.*, No. 21-0876V, 2024 WL 3425761, at *4 (Fed. Cl. Spec. Mstr. June 10, 2024 (internal citations omitted). The fact witness testimony adds even further strength to her showing. Petitioner has established that her left shoulder pain began within 48 hours.

Conclusion and Scheduling Order

Respondent does not raise any other objections to entitlement (*see generally* Rule 4(c) Report), and based on my independent review, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim. 42 C.F.R. §§ 100.3(a), (c)(10). Accordingly, she need not prove causation-in-fact. Section 11(c)(1)(C). I also find that Petitioner has satisfied all other requirements of Section 11(c) including a sufficiently severe injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D). (I do note, however, that the overall thrust of the evidence reviewed to date, as reflected in this ruling, suggest a moderately to low-severe injury – and any damages demand must take this into account.)

For the foregoing reasons, **I find that Petitioner has established entitlement and is thus entitled to compensation for a right-sided SIRVA following the right-sided administration of the flu vaccine on September 9, 2020.** Therefore, the case is now formally in the damages phase.

Petitioner has reported that the case did not involve a Medicaid lien, lost wages, or a worker's compensation claim. Status Report filed Jan. 24, 2024 (ECF No. 26).

By no later than Wednesday, October 9, 2024, Petitioner shall file a Status Report updating on the parties' efforts towards informally resolving damages. The status report shall state the date by which Petitioner provided, or intends to provide, a demand for damages to Respondent.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master